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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/557,539	11/21/2005	Martin Eberle	104610-55275(22009)	2151
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GIBBONS P.C. ONE GATEWAY CENTER NEWARK, NJ 07102			EXAMINER STOCKTON, LAURA LYNNE	
			ART UNIT	PAPER NUMBER
			1626	
			NOTIFICATION DATE	DELIVERY MODE
			12/04/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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abriggs@gibbonslaw.com
IPDocket@gibbonslaw.com

Office Action Summary	Application No. 10/557,539	Applicant(s) EBERLE ET AL.	
	Examiner Laura L. Stockton, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37 is/are allowed.
- 6) ☒ Claim(s) 23-36 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/19/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 23-38 are pending in the application.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement filed on September 19, 2007.

Response to Amendment

Comparative Reports I and II filed September 20, 2007 are insufficient to overcome the rejection of claims based upon a 35 USC 103 over Harbeson et al. {US 2004/0034037} as set forth in the last Office action because: the showing has not been presented in a Declaration under 37 CFR 1.132.

As stated in the previous Office Action, In the instant specification on page 55, starting at line 4, Applicant has compared the activity of the instant claimed compounds against two of the compounds in WO 03/066629. This WO is in the same patent family as

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Harbeson et al. {US 2004/0034037}. The showing is not persuasive since Applicant did not compare the closest compounds in Harbeson et al. Note that compounds such as Compounds 1, 4 and 6 on page 6 and Compounds 21, 24 and 26 on page 8 in Harbeson et al. are structurally closer to the instant claimed compounds than the two compounds of Example A and B found in Table 5 on page 55 of the instant specification. Applicant relying upon comparative showing to rebut *prima facie* case must compare his claimed invention with the closest prior art. In re Holladay, 199 USPQ 516, 1978.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 23-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support in the specification or the originally filed claims can be found for R¹ representing a lower alkoxy-carbonyl or carboxy-lower alkyl in newly added claim 23. Therefore, the claims lack written description as such.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 24-36 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 24, the definition of Y lacks antecedent basis from claim 23.

In claim 24, Y depends upon itself.

Claims 25, 27, 35, 36 and 38 do not conform to M.P.E.P. 608.01(m) since each claim must end with a period thereby establishing that no other subject matter is missing from the claim.

In claim 35, it is unclear what is meant by "saltz".

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-28, 30 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harbeson et al. {US 2004/0034037}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims benzimidazole compounds. Harbeson et al. teach benzimidazole compounds that are structurally similar to the instant claimed compounds (see Formula I on page 2; Formula Ia on page 5; pages 2-4, 20-22 and 24; and especially Compounds 1, 4 and 6 on page 6 and Compounds 21, 24 and 26 on page 8).

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Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP

§2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating asthma).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, asthma. The instant

claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicant's arguments filed September 20, 2007 have been fully considered but they are not persuasive.

Applicant argues that: (1) Harbeson et al. do not teach the instant claimed substituents on the 1-position of the benzimidazole compound; (2) the broadest of the disclosure of Harbeson et al.; and (3) the instant claimed compounds have unexpected properties over the compounds in Harbeson et al.

All of Applicant's arguments have been considered but have not been found persuasive. Harbeson et al. do generically teach the instant claimed substituents on the 1-position of the benzimidazole ring. See in Harbeson et al. wherein R^3 is L-R, L is an alkylene

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chain wherein a methylene is replaced by oxygen, and R is an optionally substituted phenyl (paragraphs [0026]-[0030] on page 3). Also see the preferred embodiment in paragraph [0053] on page 5.

Further, it is well established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. *In re Boe*, 148 USPQ 507, 510 (CCPA 1966). Although the disclosure in Harbeson et al. may be considered broad to some skilled in the art, Harbeson et al. would direct one skilled in the art toward the instant claimed compounds especially in view of the preferred embodiments and the specifically disclosed species. Additionally, the showing in the submitted Comparative Reports I and II filed September 20, 2007 have been found insufficient

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for reasons stated above. The rejection is deemed proper and therefore, the rejection is maintained.

Allowable Subject Matter

Claim 37 is allowed over the art of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed

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until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

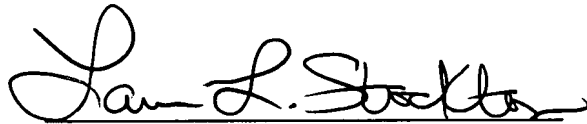
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact

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the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", with a horizontal line drawn underneath the signature.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

November 28, 2007